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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,965	02/06/2004	Keith R. Hildebrand	P-11472.00	7332

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EXAMINER	
WITCZAK, CATHERINE	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,965	HILDEBRAND ET AL.	
	Examiner	Art Unit	
	Catherine N. Witczak	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/3/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

6/3/06

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17, 28-30, 38-54, and 64-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Mayberg (US 2003/0149450).

Claims 1 and 38: Mayberg discloses a drug infusion catheter disposed at a central nervous system site, coupled to a drug delivery pump that discharges a dosage of sympatholytic cardiovascular agent in paragraphs 0013, 0027, 0034 and 0038.

Claims 2 and 39: Mayberg discloses in paragraph 0032 implanting a physiologic sensor to derives a parameter associated with heart failure and use this parameter to adjust dosage.

Claims 3 and 40: Mayberg discloses in paragraph 0040 the physiologic sensor being an arterial blood pressure sensor.

Claims 4, 12, 14, 41, 49, and 51: Mayberg discloses in paragraph 0040 determining electrical alternans.

Claims 5-11, 13, 16, 17, 29, 30, 42-48, 50, 53, 54, 66, and 67: Mayberg discloses in paragraph 0049 using clonidine as a pharmaceutical agent, which is an alpha2-adrenergic agonist.

Claims 15, 28, 52, and 65: Mayberg discloses in paragraph 0034 delivering the agent to a subarachnoid space of the spinal chord.

2-6-06

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-37 and 68-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayberg (US 2003/0149450) as modified by Kim (US 2004/0073197).

Mayberg discloses the claimed invention except for clonidine being delivered into the central nervous system by intrathecal infusion. Kim teaches that it is known to use 100 mcg/day (0.1 mg/day) of clonidine in order to provide pain treatment in paragraph 0066. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Mayberg, by providing a dosage of 100 mcg/day of clonidine as taught by Kim, since such a modification would provide the method with a dosage of clonidine that would provide pain treatment.

Claims 1, 18-21, 38, and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayberg (US 2003/0149450) as modified by Elsberry (US 2001/0027309).

Claims 1and 38: Mayberg discloses a drug infusion catheter disposed at a central nervous system site, coupled to a drug delivery pump that discharges a dosage of sympatholytic cardiovascular agent in paragraphs 0013, 0027, 0034 and 0038.

Claims 19 and 56: Mayberg discloses in paragraph 0032 implanting a physiologic sensor to derives a parameter associated with heart failure and use this parameter to adjust dosage.

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Claims 20, 21, 57 and 58: Mayberg discloses in paragraph 0049 using clonidine as a pharmaceutical agent, which is an alpha2-adrenergic agonist.

Mayberg discloses the claimed invention except for the external drug delivery pump. Elsberry teaches that it is known to use an external drug delivery pump. Elsberry does not explicitly state why an external drug delivery pump is used, but it appears that it is used to allow the patient/caregiver easier access to the pump. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Mayberg with an external drug delivery pump as taught by Elsberry, since such a modification would provide the method with easier manner of accessing the pump [Claims 18 and 55].

Claims 1, 22-27, 38, and 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayberg (US 2003/0149450) as modified by Hartlaub et al (US 2001/0037083).

Claims 1and 38: Mayberg discloses a drug infusion catheter disposed at a central nervous system site, coupled to a drug delivery pump that discharges a dosage of sympatholytic cardiovascular agent in paragraphs 0013, 0027, 0034 and 0038.

Claims 23 and 60: Mayberg discloses in paragraph 0032 implanting a physiologic sensor to derives a parameter associated with heart failure and use this parameter to adjust dosage.

Claims 24, 25, 61, and 62: Mayberg discloses in paragraph 0038 providing a patient activator to command the delivery of the sympatholytic agent to the CNS site.

Claims 26, 27, 63, and 64: Mayberg discloses in paragraph 0049 using clonidine as a pharmaceutical agent, which is an alpha2-adrenergic agonist.

Mayberg discloses the claimed invention except for the external drug delivery pump. Hartlaub et al teach that it is known to use an implantable drug delivery pump. Hartlaub et al do not explicitly state

why an external drug delivery pump is used, but it appears that it is used so that the patient does not need wear an external pump. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Mayberg with an implantable drug delivery pump as taught by Hartlaub et al, since such a modification would allow the patient to not have to wear an external pump [Claims 22 and 59].

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-74 of copending Application No. 10/903,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications deal with methods of treating conditions related to heart failure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine Witczak
Junior Examiner
Art Unit 3767

2-6-05

Kevin C. Sirmons